

*Certified copies not received:

Acknowledgement is made of a claim for domestic priority under 354, 200 cm.



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Washington, D.C. 20231 APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTORNEY DOCKET NO. 08/466,343 06/06/95 LI 325800-449 EXAMINER BASHAM, D 18N2/0923 ELLIOT M OLSTEIN PAPER NUMBER ART UNIT CARELLA BYRNE BAIN GILFILLAN CECCHI 10 STEWART & OLSTEIN-6 BECKER FARM ROAD DATE MAILED: 12 ROSELAND NJ 07068 09/23/96 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS **OFFICE ACTION SUMMARY** Responsive to communication(s) filed on ____ This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213. A shortened statutory period for response to this action is set to expire______ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). **Disposition of Claims** is/are pending in the application. Claim(s) __ Of the above, claim(s) ______ is/are withdrawn from consideration. Claim(s) ___ __ is/are allowed. ☐ Claim(s) ______ _ is/are rejected. Claim(s) _____ are subject to restriction or election requirement. ☐ Claims **Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. ☐ The drawing(s) filed on ___ _____ is/are objected to by the Examiner. The proposed drawing correction, filed on _____ is approved disapproved. ☐ The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

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DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report. Correction is required.

Election/Restriction

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-6, drawn to polynucleotides, vectors, host cells, process for producing a polypeptide, process for making host cells, classified in Class 435, subclass 69.1.
 - II. Claims 7, 8 and 19, drawn to polypeptide, classified in Class 530, subclass 350.
 - III. Claim 9, drawn to an antibody, classified in Class 530, subclass 388.22.
- IV. Claims 10 and 12, drawn to compounds that activate the polypeptide and a method of treatment using the compounds, classified in Class 514, subclass 2.
- V. Claims 11 and 13, drawn to compounds that inhibit activation of the polypeptide and a method of treatment using the compounds, classified in Class 514, subclass 2.
- VI. Claims 14, drawn to the administration to a patient of DNA encoding a protein which activates the polypeptide, i.e., gene therapy, classified in Class 514, subclass 44.
- VII. Claims 15, drawn to the administration to a patient of DNA encoding a protein which inhibits the activation the polypeptide, i.e., gene therapy, classified in Class 514, subclass 44.
- VIII. Claims 16 and 17, drawn to a method for identifying modulating effector molecules, classified in Class 435, subclass 7.2.

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- IX. Claim 18, drawn to method of diagnosis of mutations in nucleic acid sequences, classified in Class 435, subclass 7.1.
- X. Claim 20, drawn to diagnosis by determining the presence of the polypeptide in a sample from host, classified in Class 436, subclass 86.

The inventions are distinct, each from the other because of the following reasons:

Inventions VIII, IX and X are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes.

Inventions VI and VII are independent and distinct from Inventions VIII, IX and X because the methods of Inventions VI and VII are practiced with materially different process steps for materially different purposes as compared to the methods of Inventions VIII, IX and X. Invention VI is independent and distinct from Invention VII because each requires distinct material compositions and have process steps which have opposite effects.

Inventions IV and V are independent and distinct from Inventions IX and X because neither the material compositions nor process steps of the former inventions are produced or used in the practice of the methods of Inventions IX and X. Invention IV is independent and distinct from Invention V because each requires distinct material compositions and have process steps which have opposite effects.

Inventions IV and V are independent from Inventions VI and VII because neither the material compositions nor process steps of the former inventions are produced or used in the practice of the methods of Inventions VI and VII.

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Inventions VI, VII and VIII are independent and distinct from Inventions I and II because none of the compositions of the latter inventions are used in or produced by the methods of Inventions VI, VII and VIII.

Invention III is independent and distinct from Inventions IV, V, VI, VII and X because the antibody of Invention III has independent utility as a reagent for ELISA.

Invention VIII is independent from Invention III because the composition of the latter invention is not used in or produced by the method of Invention VIII.

Invention IX is independent and distinct from Inventions II and III because none of the compositions of the latter inventions are used in or produced by the method of Invention IX.

Invention IX is independent and distinct from Invention I because Invention I has an independent utility as a means of producing an encoded polypeptide.

Invention X is independent and distinct from Invention II because the polypeptide of Invention II has independent utility as an antigen for antibody generation. Invention X is independent and distinct from Inventions I because the composition of the latter invention is not used in or produced by the method of Invention X.

Inventions I, II, III, IV and V are independent and distinct, each from the other because they are compositions which possess characteristic differences in structure and function and each have independent utilities, that are distinct for each material composition, which are not interchangeable.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications, restriction for examination purposes as indicated is proper.

- Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).
- A telephone call was made to Jay Mullins on September 18, 1996 to request an oral 4. election to the above restriction requirement, but did not result in an election being made.
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daryl A. Basham, Ph.D., whose telephone number is (703) 305-2150. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Stephen Walsh, Ph.D., can be reached on (703) 308-2957.

The fax phone number for this group is (703) 308-0294. Any inquiry of the general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

dab

September 19, 1996

GROUP 1800